

## **REMARKS**

Applicants respectfully request entry of the above amendments and reconsideration of the following arguments pursuant to 37 C.F.R. § 1.111.

### **1. Status of the Claims**

Claims 1-20 stand pending. Claims 10-11 and 18-20 stand withdrawn. Claims 1-9 and 12-17 stand rejected. Claims 2-9, 12, 14-17 stand objected to.

Upon entry of the present amendments, claims 2-5, 10-11, and 18-20 stand canceled. Applicants amend claims 1, 6-9, and 12-17 to more precisely recite the claimed subject matter. Support for the amendments can be found at least, for example, from the originally filed claims. For example, Applicants amend claim 1 to incorporate limitations from claim 2. Applicants do not believe that the amendments add prohibited subject matter that is unsupported in the Specification as filed.

The claims have been amended without prejudice to, or disclaimer of, the canceled subject matter. Applicants reserve the right to file a continuation or divisional application on any subject matter canceled by way of amendments.

### **2. Objection to the Specification**

The Office indicates in the Office Action Summary that the Specification is objected to. However, the objection to the Specification is unaddressed in the Office Action. For the clarity of the record, the Office is respectfully request to clarify the issue with its next communication.

### **3. Priority Documents**

Applicants appreciate the Office's acknowledgement that certified copies of the priority documents have been received.

### **4. Acceptance of Drawings**

Applicants appreciate the Office's acknowledgement that the drawings filed are deemed

acceptable.

**5. Acknowledgement of Information Disclosure Statements**

Applicants appreciate the acknowledgement of the Information Disclosure Statements (IDS) filed April 26, 2007; April 13, 2007; and June 15, 2006. The Office lines through two references in the IDS submitted April 13, 2007, alleging that the publication dates are not provided.

Applicants submit herewith an updated PTO-1449 form that includes the full citation of the two references. The Office is respectfully requested to acknowledge the consideration of the references with the next communication. No fee is believed to be necessary for this submission.

**6. Objections to the Claims**

The Office objects to claims 2-5 and 7 for allegedly being drawn to a non-elected invention. Office Action, page 3.

Upon entry of the amendments, claim 7 no longer recites *Linaria bipartite*; and claims 2-5 stand canceled. The objection is thus moot.

The Office objects to claims 2, 4-9, 12, and 14-17 for allegedly improper use of articles ("a" or "the"). *Id.* Applicants appreciate the Office's suggestion and amend claims 6-9, 12, and 14-17 by using proper articles. Additionally, claims 2 and 4-5 stand canceled. The objection is moot.

The Office objects to claim 12 for allegedly misspelling the word "vegetatively." *Id.* Claim 12 is amended to omit the word. The objection is moot.

Applicants respectfully request withdrawal of the objections and allowance of the claims.

**7. Rejection of the Claims under 35 U.S.C. § 112, Second Paragraph**

The Office rejects claims 14 and 17 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claim 14 allegedly fails to set forth any steps involved in the claimed method / process. *Id.* Claim 17 is allegedly incomplete for omitting essential steps. *Id.*, at 4.

Upon entry of the amendments, claim 14 recites at least an active step, *i.e.*, “expressing the gene.” Amended claim 14 thus complies with the definiteness requirement of § 112. Amended claim 17 recites at least two essential steps for altering flower color to yellow in a plant, *i.e.*, “introducing” and “expressing” the recited gene. Amended claim 17 thus complies with the definiteness requirement of § 112.

Accordingly, Applicants respectfully request withdrawal of the indefiniteness rejection and allowance of the claims.

## **8. Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph**

### **8.1. Written Description Rejection**

The Office rejects claims 1, 3-9, and 12-17 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that:

- 1) The application fails to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus;
- 2) The application does not describe a representative number of polynucleotide sequences encoding any aureusidin synthase; and
- 3) There is a lack of description of the necessary elements essential for the protein encoded by SEQ ID NO: 1 or any aureusidin synthase.

Office Action, pages 6-7.

Applicants traverse the rejection to the extent as it may be applied to the amended claims. Claim 1 as amended recites an isolated nucleic acid encoding a protein having activity of transferring a sugar to the chalcone 4'-position (4'CGT enzyme activity), wherein the 4'CGT having an amino acid sequence of SEQ ID NO: 2. Applicants' traversal is based on the following grounds.

#### **8.1.1. The Office misstates the standard for compliance with the written description requirement.**

The Federal Circuit has held that *working examples* covering the full scope of the claims are *not* required for written description to be considered adequate:

A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before.

*Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 U.S.P.Q.2d 1001, 1007 (Fed. Cir. 2006). The Office's requirement for specific examples for each and every variant encompassed by the claim ***explicitly contradicts*** this holding.

8.1.2. The amended claims comply with the appropriate standards for written descriptions.

To satisfy the written description requirement, Applicants are required to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicants were in possession of the invention. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

For amended claims reciting a gene encoding a 4'CGT enzyme, the written description requirement is satisfied. With the aid of a computer, a skilled in the art could have identified all the gene sequences that encode a protein having an amino acid sequence SEQ ID NO: 2. The present application has demonstrated that the protein having an amino acid sequence of SEQ ID NO: 2 is a 4'CGT enzyme, which possess the claimed enzymatic activity—transferring a sugar to the chalcone 4'-position. Accordingly, a skilled artisan would conclude that Applicants was in possession of the claimed genus at the time the application was filed. *See Example 11, Written Description Training Materials*, Revision 1, March 25, 2008 (available at <http://www.uspto.gov/web/menu/written.pdf>), pages 37-42.

As to the rejection of claim 17, amended claim 17 recite, *inter alia*, a gene encoding “*Antirrhinum majus* aureusidin synthase.” A skilled artisan would have known that Applicants had possession of the claimed method, because there is only one known aureusidin synthase from *A. majus*. *See Nakayama T. et al.*, 290 SCIENCE 1163 (2000) (submitted in the IDS of April 13, 2007). Accordingly, the rejection of claim 17 is partially moot as to allegedly inadequate

description of aureusidin synthase.

For all the forgoing reasons, amended claims 1, 6-9, and 12-17 comply with the written description requirement. Claims 3-5 stand canceled, mooted the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

## **8.2. Enablement Rejection**

The Office rejects claims 1-9 and 12-17 under 35 U.S.C. § 112, first paragraph, as allegedly failing to be enabling.

Applicants traverse the rejection to the extent as it may be applied to the amended claims. The traverse is specifically under the following grounds.

### **8.2.1. The claimed methods have been reduced to practice.**

The Office posits that the claimed invention allegedly has not been reduced to practice. Specifically, the Office alleges, "Applicants have not transformed any plant with a nucleic acid encoding any protein that transfers a sugar to the chalcone 4'-position to produce a plant with a *useful* agronomic phenotype." Office Action, page 8 (emphasis added).

Applicants disagree. First, the Office overlooks Examples 10 and 14 on pages 32-34 and 39-42 of the Specification. In these two examples, Applicants provide description as to (1) the transformation of *torenia* with various nucleic acid constructs comprising a 4'CGT gene and a aureusidin synthase (AS) gene; and (2) identification of various transformants with altered colors. The Office assertion is thus unsubstantiated. Applicants do reduce to practice the claimed methods. Second, by alleging that Applicants failed to produce a plant with a useful agronomic phenotype, the Office apparently makes the enablement rejection with an unsupported utility rationale. The Office is respectfully requested to make an independent rejection under 35 U.S.C. § 101, so that Applicants can fully respond.

8.2.2 The Office's assertion of unpredictability of the art is unsupported.

The Office alleges that the state-of-the-art teaches the unpredictability of the claimed methods. Office Action, page 8. The Office relies on **Ono** E. et al., 103 PROC NATL ACAD SCI USA 11075 (2006) ("Ono"). Specifically, the Office alleges that the transformation of a torenia plant with a 4'CGT-containing construct in Ono did not alter the flower color.

Applicants disagree. The Office appears to mischaracterize Ono. Ono was published on July 18, 2006, more than two years *after* the foreign priority date of the present application, December 17, 2003. A skilled artisan reviewing Ono should have been aware of the present application. The present application provides description that the transformation of a torenia plant with a construct comprising both 4'CGT and AS did alter the flower color. *See* section 8.2.1 *supra*. Furthermore, FIGs. 1-2 of the present application illustrate pathways for pigments affecting flower colors. As shown in FIG. 1, both 4'CGT and AS enzymatic activities are necessary to convert 4,2',4',6'-tetrahydroxychalcone (THC) to aureusidin 6-glucoside, which is responsible for the yellow color. Accordingly, a skilled artisan would have understood that an AS gene is necessary for such a transformed plant absent of the endogenous enzyme activity.

The relevant section of Ono is "**UGT88D3 Functions as a 4'CGT in Vivo.**" Ono, paragraph bridging pages 11077-78. The authors performed the experiment to show that the UGT88DC locus encodes a glucosyltransferase functioning as a 4'CGT enzyme *in vivo*. The authors did not intend to test whether introduction of the 4'CGT gene alone is sufficient to alter flower color in a transformed plant. Accordingly, Ono fails to undermine Applicants' claims from the aspect of unpredictability.

8.2.3. It does not require undue experimentation to practice the full scope of the amended claims.

The Office alleges that undue experimentation would be required to practice the claimed invention for the lack of guidance and examples, the unpredictability in the art, and teachings of the state-of-the-art. Office Action, page 10. Specifically, the Office alleges that:

- 1) the prediction of protein structure / function from sequence data is extremely complex;

- 2) the present application fails to disclose how to make or isolate any of the sequence encompassed by the broad claim language; and
- 3) the application fails to provide guidance as to which amino acids of the protein encoded by SEQ ID NO: 1 can be altered or deleted.

*Id.*, at 9.

Applicants disagree. Enablement is determined by weighing several factors to determine whether undue experimentation would be required to make or use the claimed invention. *See In re Wands*, 858 F.2d 731, 736, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Furthermore, if the experimentation is routine in nature and the techniques necessary to perform the experimentation are well known to a skilled artisan, the amount of experimentation to practice the full scope of the claimed invention is not undue. *See Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998).

Upon entry of the present amendment, claim 1 recites an isolated nucleic acid that (1) encodes a 4'CGT enzyme, and (2) encodes a 4'CGT enzyme having an amino acid sequence of SEQ ID NO: 2. With the aid of a computer, it would have been routine for a skilled artisan to identify all the nucleotide sequences encoding a protein having an amino acid sequence SEQ ID NO: 2. The present application has demonstrated that the protein having an amino acid sequence is a 4'CGT enzyme that is capable of transferring a sugar to the chalcone 4'-position. Accordingly, an ordinarily skilled in the art would *not* perform undue experimentation to obtain recited nucleic acids.

As to the method claims, the Specification provides at least one example of altering flower color by introducing a 4'CGT gene and a AS gene into a plant. *See e.g.*, section 8.2.1 *supra*. It is clear from the Specification that it does not require undue experimentation to practice the full scope of the claims as amended.

#### 8.2.4. Amended claims 14 and 17 are enabled.

The Office's rejection of claims 14 and 17 is partially premised on the alleged indefiniteness. Office Action, pages 9-10. Upon entry of the present amendments, claim 14

recites at least an active step, *i.e.*, “expressing the gene.” Amended claim 17 recites at least two essential steps for altering flower color to yellow in a plant, *i.e.*, “introducing” and “expressing” the recited gene. Amended claims 14 and 17 thus comply with the definiteness requirement of § 112. *See* section 7 *supra*. Furthermore, amended claims 14 and 17 comply with the enablement requirement in view of the above arguments in section 8.2.3.

For all the forgoing reasons, amended claims 1, 6-9, and 12-17 comply with the enablement requirement. Claims 2-5 stand canceled, mooted the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

**9. Rejection of the Claims Under 35 U.S.C. § 101**

The Office rejects claim 9 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The recited “host cells transformed” allegedly read on a human being. Office Action, page 11. Applicants appreciate the Office’s amendment suggestion and have amended claim 9 to recite “an isolated host cell transformed.” The rejection thus stands mooted.

The Office rejects claim 12-13 and 15-16 under 35 U.S.C. § 101 as allegedly being directed to non-statutory matter. The recited “progeny” allegedly reads on the naturally-occurring progeny. *Id.* Applicants appreciate the Office’s suggestion. Upon entry of the amendments, claims 12 and 15 recite the progeny that (1) derives from the claimed plant, and (2) comprises the claimed gene. Thus, the rejection stands mooted.

The Office rejects claim 14 under 35 U.S.C. § 101 as allegedly failing to set forth any steps involved in the process. *Id.*, at 4. Upon entry of the amendments, claim 14 recites at least an active step, *i.e.*, “expressing the gene.” Thus, the rejection is mooted.

The Office rejects claims 1-7 and 12-17 under 35 U.S.C. § 101 as allegedly being directed to non-statutory matter. The Office alleges that “a gene” does not indicate the involvement of human beings. *Id.*, at 11. Applicants appreciate the Office’s amendment suggestion and have amended claim 1 to recite “an isolated gene.” Additionally, claims 2-5 stands canceled. Thus, the rejection is mooted.



Accordingly, Applicants respectfully request withdrawal of the subject matter rejection and allowance of the claims.

### **CONCLUSION**

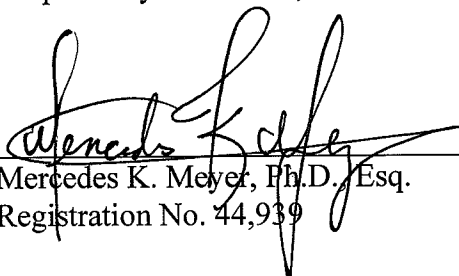
Should the Office have any questions or comments regarding Applicants' amendments or response, please contact Applicants' undersigned representative at (202) 842-8821. Furthermore, please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully Submitted,

Date: December 23, 2009

By: \_\_\_\_\_

  
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